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Section II (Remarks)A. Subject Matter Indicated As Allowable

In the November 13, 2006 Office Action, claims 27-43, 53 and 54 were indicated to be allowable, and claims 11-16, 46, 49, and 52 were objected to as depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

B. Summary of Examiner Interview of February 16, 2007

The undersigned extends appreciation to the Examiner for making time for an in-person Examiner Interview on February 16, 2007. A summary of the interview follows. The Olson reference (U.S. Patent No. 5,122,129) was discussed relative to the subject matter of independent claims 9 and 44, particularly with regard to the limitations claimed in the alternative in such independent claims. Comparison of method claims 55 and 59 to the device claims was further discussed, with the possibility of obtaining rejoinder of claim 55 upon amendment of independent claims 9 and 44. Possible amendment to claim 59 (*i.e.*, to recite specific threshold of gas pressure of greater than about 1 atm) to facilitate rejoinder to the device claims was also discussed.

C. Response to Restriction Requirement

In the November 13, 2006 Office Action, a restriction requirement was imposed against claims 55-62. Applicants hereby request reconsideration and withdrawal of the restriction requirement for the reasons stated below.

The November 13, 2006 Office Action at page 2 thereof bases the restriction requirement as applied to claims 55-62 on the alleged *independence OR distinctness* of such claims from the invention of claims 9-54, and thereby ignores the statutory criteria for restriction in 35 USC 121, which requires that:

"[I]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."

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The statute therefore requires as a basis for legally permissible restriction that the subject matter of respective claims be BOTH independent and distinct. Neither criterion alone is sufficient. Both must be present in order for the restriction requirement to be proper under the statute.

The examiner's attention is directed in this respect to the provisions of MPEP Section 802.01 (Meaning of "Independent" and "Distinct"), which states, *inter alia*:

**"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect..."**

It is apparent from this provision of the MPEP that the subject matter of the claims 55-62 is not "independent" within the meaning of 35 USC 121 – particularly where (as here) there exists broad overlap and close similarity between the subject matter of claims 55-62 and the subject matter of amended claims 9-54 – and that therefore Groups I and II are NOT properly restricted.

The examiner alleged that "[1] the claimed device comprises features claimed in the alternative that are not present in the claimed method, and [2] the method claims present limitations that are not recited in the device claims." November 13, 2006 Office Action, page 2, paragraph 3. Statement [1] is misguided in that each of the alternative features cited in the independent claims is recited separately in dependent claims, thus rendering each such feature mandatory in at least one claim. Moreover, statement [2] is misleading in that method claims 55-62 include at least certain claims that correspond quite closely to counterpart device claims, such as indicated below in the following comparison of representative claims.

<i>Representative Device Claim</i>	<i>Representative Method Claim</i>
51. An apparatus comprising: a <u>hollow connector</u> having an interior wall defining a fluid chamber for the passage of fluids, wherein the hollow connector comprises an inlet end and an outlet end, wherein the inlet end is configured to engage a container and the outlet end has an aperture therethrough for the egress of the fluids from the container; and a <u>membrane</u> having an interior	59. A method comprising the steps of: enclosing a <u>piercing element</u> of a <u>hollow connector</u> within a <u>membrane housing</u> sealed from an external environment, the piercing element being adapted to puncture the membrane housing; and inserting a <u>gas that is essentially sterile</u> into the membrane housing at a <u>gas pressure of greater than about 1 atm to generate</u> , when the piercing element punctures

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<p>surface <u>defining a housing chamber</u> for housing the hollow connector with a <u>gas that is essentially sterile</u>,</p> <p>wherein ... the <u>gas has a pressure of greater than about 1 atm</u> when inside the housing chamber ... [and]</p> <p>wherein the hollow connector comprises a <u>piercing element</u> disposed within the housing chamber along the outlet end.</p>	<p>an opening in the membrane housing, a <u>laminar flow of gas out of the membrane housing</u> along sides of the opening.</p>
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<i>Representative Device Claim</i>	<i>Representative Method Claim</i>
<p>37. A system comprising:  a first delivery assembly comprising:  a <u>first container</u> having an opening, the first container to hold a liquid;  a hollow connector having an interior wall defining a fluid chamber for the passage of the liquid, wherein the <u>hollow connector comprises an inlet end</u> and an outlet end, wherein the inlet end is <u>configured to engage the first container</u> and the outlet end has an aperture therethrough for the egress of the liquid from the container; and  a <u>membrane</u> having an interior surface defining a housing chamber <u>for housing the hollow connector with a gas that is essentially sterile, wherein the gas has a pressure of greater than about 1 atm when inside the chamber</u>;  wherein the <u>hollow connector comprises a needle or a cannula</u>.</p>	<p>55. A method comprising the steps of:  connecting a <u>source container</u> adapted to hold a fluid to an inlet end of a <u>hollow connector comprising a piercing element</u> adjacent to an outlet end of the hollow connector, with the piercing element disposed in an <u>essentially sterile gas at a pressure greater than about 1 atm, the gas being contained by a membrane</u>;  positioning the outlet end of the <u>hollow connector adjacent to a target container</u>;  puncturing an opening in the membrane with the <u>piercing element</u>, wherein puncturing the opening generates a laminar flow of the gas along the sides of the opening; and  <u>extending at least a portion of the hollow connector into the target container</u>.</p>

Comparing device claim 55 against method claim 59, it should be recognized that a “gas [that] has a pressure of greater than about 1 atm when inside the [membrane] housing chamber” of device claim 51 is a “gas [having a] pressure of greater than about 1 atm to generate ... a laminar flow out of the membrane housing... [when punctured]” of claim 59. The close similarity – and therefore the lack of “independence” – between such claims is unmistakable.

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Likewise, comparing device claim 37 against method claim 55, it should be recognized that the “hollow connector compris[ing] a needle or cannula” in claim 37 corresponds to the “hollow connector comprising a piercing element” of claim 55. As before, the close similarity – and therefore the lack of “independence” – between such claims is unmistakable.

Given the unmistakable similarity and non-independence between, for example, claims 51 and 59, and between claims 37 and 55, it is pointed out that the subject matter of the respective method claims imposes no serious burden of searching (i.e., under MPEP 808.02) on the examiner, since the substance of the method claims 55-64 certainly should have already been searched by the examiner in connection with claims 9-54. It is incumbent on the examiner to “explain why there would be a serious burden on the examiner if restriction is not required” (MPEP 808.02) or simply withdraw the restriction requirement and rejoin the method claims.

According to the MPEP section 803:

**“[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” MPEP § 803.**

Under the applicable criterion of this MPEP provision, the examiner is required to submit method 55-64 to examination on the merits.

#### D Rejections Under 35 U.S.C. 102

In the November 13, 2006 Office Action, claims 9, 10, 17-26, 44, 45, 47, 48, 50, and 51 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. 5,122,129 to Olson et al. (“Olson”). Such rejections are traversed, as detailed below.

##### I. Law Regarding Anticipation

“Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d

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1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, “[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo, N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Disclosure of Olson

Olson discloses a sampler coupler device having a plastic sheath with a descending skirt that is removably mountable via a threaded connection to an access port of a four-way stopcock. Olson col. 3, lines 62-68 & col. 4, lines 51-54. Within the sheath 17, a hollow needle 21 is enveloped within a rubber-like prolate drip boot 22 that serves to prevent contamination of the pointed end of the needle 21, and to contain any fluid or gas drippage from the needle. Olson, col. 4, lines 7-25. The threaded end of the coupler device includes an ... internal thread 19, as shown in FIG. 4 ... [that] engage[s] the threaded lip 30 [of a four-way stopcock], as shown in FIG. 7, until the conical feature 12, as shown in FIG. 2, bottoms tightly into the conical bore 29, as shown in FIG. 7, effecting a seal. Olson, col. 6, lines 29-37. The sample coupler device is adapted to mate with an evacuated container (e.g., a vial) such that the needle pierces a cap of the vial to enable fluid communication with its interior. FIG. 1 of Olson is reproduced below, followed by Olson FIGS. 4-6.

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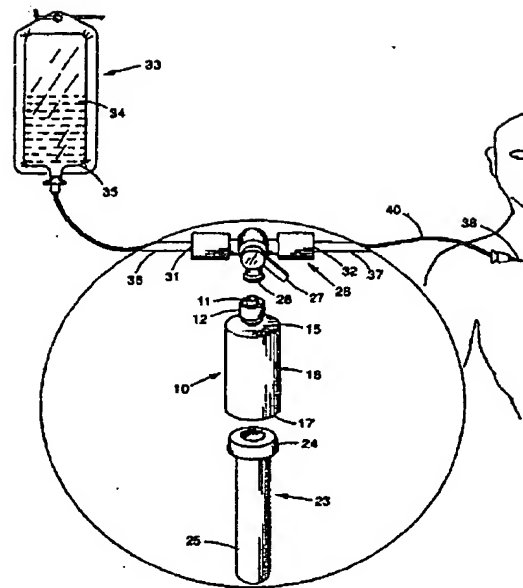
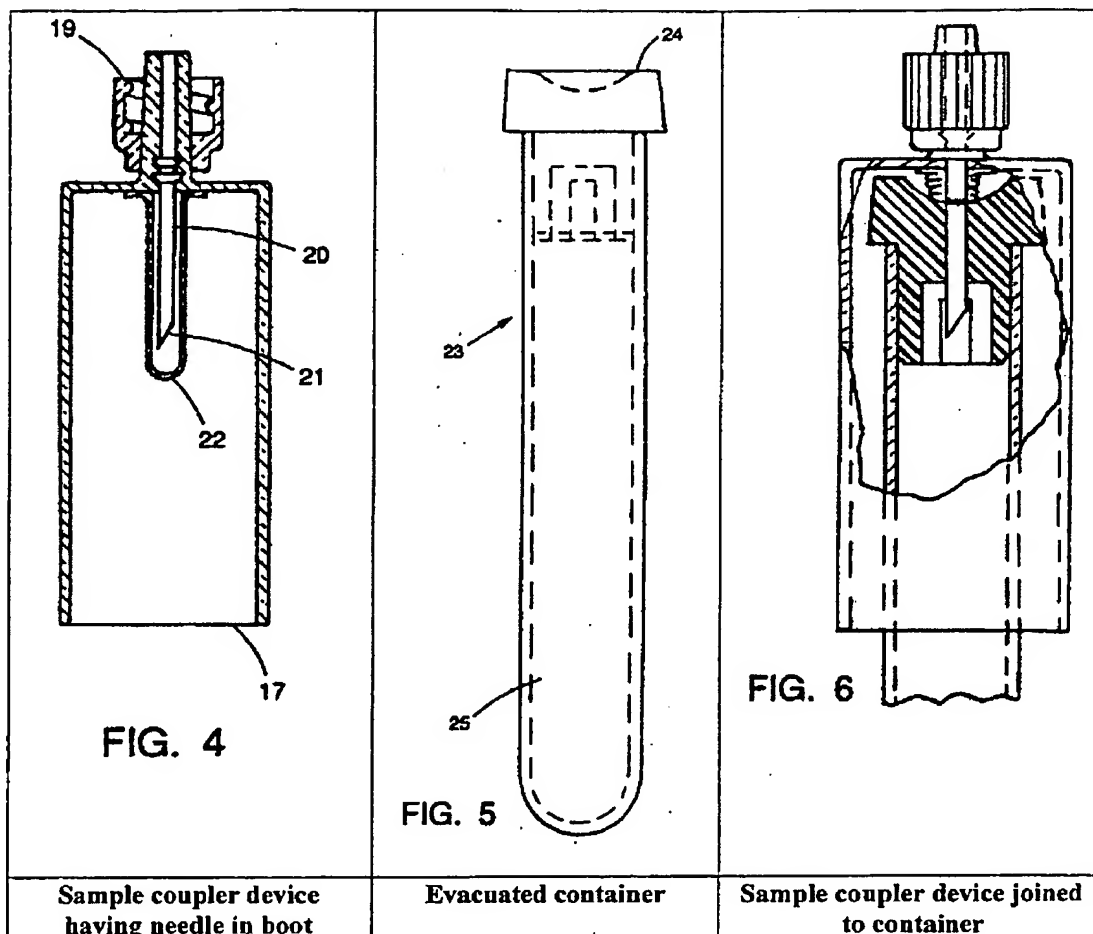


FIG. 1

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Olson's invention provides a "sampler coupler device [that] allows for samples of blood, fluids or gases to be collected from a closed, arterial style feed-system, while also preventing contamination of the collected sample through exposure to an atmosphere outside of the closed system." Olson, Col. 3, lines 52-56. Olson Figure 1 (reproduced below) illustrates a system in which:

[a] four-way stopcock 26 has one end of transport pipe 36 attached to its reservoir pipe port 31, with the opposite end of transport pipe 36 attached to the medicament reservoir 35. The four-way stopcock 26 has one end of arterial transport pipe 37 attached to its arterial pipe port 32, with the opposite end of arterial transport pipe 37 attached to the artery entry needle 38."

Olson, col. 6, lines 6-13.

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2. Meaning of the term "latch" as contained in the claims

In the November 13, 2006 Office Action, at page 4 thereof, the examiner indicated that she "interprets applicant's claim drawn to a latch between the container and the connector to be a broad recitation of the threaded connection pointed out above" (i.e., the threaded connection 19/30 of Olson between the connector and the container tube via tube 36, with reference to FIGS. 3 and 4 of Olson). The Examiner's interpretation of the term "latch" in this regard is incorrect.

It is well-settled that a patent applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. MPEP 2111.01; *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

The term "latch" is discussed in the present application at paragraph [0024], as reproduced in pertinent part below:

[0024]The latch 120 is between the coupling 122 and the first connector 110. **The latch 120 may be a clamp or break valve.** For example, the coupling 122 may include a cover that is broken by a break valve when the break valve is rotated. Therefore, **the substance 104 does not dispense into the first connector 110 until the latch 120 is rotated to allow for such dispensing.**

Given this context, any definition of the term "latch" as applied to the claims should include a *structure that selectively allows dispensing.*

4. Patentability of Amended Claim 9 over Olson

Claim 9 has been amended herewith to eliminate the alternative "latch" and "threaded connection" limitations, thus leaving (1) a "gas having a pressure greater than about 1 atm when inside the housing chamber" and (2) a "membrane [having] a partial slit or cut" limitations as the only alternatives in the wherein clause. **Olson fails to disclose either of the foregoing limitations (1) and (2),** as formally recognized by the Examiner in paragraphs 7 and 9 of the November 13, 2006 Office Action, reciting that "the prior art fails to disclose or suggest the connector claimed by applicant with a membrane over the hollow connector creating a chamber



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with a gas contained therein, wherein the gas has a pressure of greater than 1 atm inside the chamber” ... “or the membrane has a ...partial slit.”

Because Olson fails to disclose either (1) a “gas having a pressure greater than about 1 atm when inside the housing chamber” or (2) a “membrane [having] a partial slit or cut,” Olson fails to disclose “each and every element of the claimed invention, arranged in the claim” (*Lindemann, supra*) as required to support a rejection of amended claim 9 for anticipation under 35 U.S.C. 102. Accordingly, amended claim 9 is not anticipated by Olson, such that the Section 102(b) rejection of claim 9 should be withdrawn.

Since the balance of claims substantively examined in the November 13, 2006 Office Action depend from claims 9 or 44 (whether directly or indirectly) and inherently include all of the limitations of the independent claims, none of these claims can be anticipated by Olson. Withdrawal of all pending rejections under 35 U.S.C. 102(b) is warranted, and respectfully requested.

**E Request for Rejoinder of Method Claims**

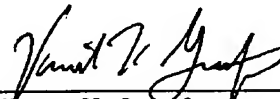
In the event that the restriction requirement is maintained, Applicant requests rejoinder of method claims 55-62 under MPEP 821.04 on identification of allowable subject matter in the elected claims, particularly in view of the amendments made to independent claims 9 and 44 to promote the allowance thereof.

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**CONCLUSION**

Method claims 55-62 should be substantively examined following either withdrawal of the restriction requirement or rejoinder of the method claims to (device) claims 9-54. Claims 9-54 as amended herewith have been fully patentably distinguished over the art, and are in form and condition for allowance. Favorable action by the Examiner consistent with the foregoing is respectfully requested. If the Examiner has any inquiries incident to the formal allowance of the present application, she is invited to telephone the undersigned at (919)419-9350.

Respectfully submitted,



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